

REMARKS

In the Office Action mailed June 13, 2007, the Examiner rejected Claims 25, 26, 28-42, 45-55 and 65 under 35 U.S.C. §102(a) as being anticipated by Bielinska, et al., 2000 Biomaterials Vol. 21, Issue 9, pages 877-887 (hereinafter, “the Bielinska reference”), rejected Claims 25, 26, 28-42, 45-55 and 65 under 35 U.S.C. §103(a) in light of Foldvari, et al., (2000) J. Controlled Release, Volume 66, 15 May 2000, pages 199-214 (hereinafter, “the Foldvari reference”), Baker et al., (1996) Nucleic Acids Research vol. 24, pages 2176-2182 (hereinafter, “the Baker reference”), and U.S. Patent No. 6,267,987 (hereinafter, “the Park patent”). Each rejection is addressed below.

I. Rejection of Claims 25, 26, 28-42, 45-55 and 65 under 35 U.S.C. §102(a)

Claims 25, 26, 28-42, 45-55 and 65 were rejected under 35 U.S.C. §102(a) as being anticipated by Bielinska, et al., 2000, Biomaterials 21:877-887 (hereinafter, “the Bielinska reference”). The Applicants disagree with the Examiner. In response to a 35 U.S.C. §102(a) rejection in the Office Action mailed January 13, 2005, the Applicants submitted a 37 C.F.R. §1.132 Declaration dated July 11, 2005 from Inventor Roessler asserting that the Bielinska reference is a publication of the Applicants’ own work published within the year before the filing date of the present application, and therefore, is not prior art. In the Restriction Requirement mailed September 28, 2005, the Examiner accepted the Roessler Declaration, withdrew the Bielinska reference as prior art, and stated, “The rejection of claims 1-15, 25-29, 32-45 and 60-64 under 35 U.S.C. 102(a) as being anticipated by Bielinska...is withdrawn in light of the 132 declaration by Blake J. Roessler for and on behalf of co-inventors...” Restriction Requirement mailed January 13, 2005, page 2.

In the Office Action mailed January 27, 2006, the Examiner recited the Bielinska reference against the claimed invention in a 35 U.S.C. §102(b) rejection. In the Response filed March 24, 2006, the Applicants requested the rejection be withdrawn in light of the Examiner’s previous acknowledgement that the Bielinska reference is a publication of the Applicants’ own published within the year before the filing date of the present application, and therefore, is not prior art (see, Restriction Requirement mailed January 13, 2005, page 2). The Examiner withdrew the rejection in the June 16, 2006 Office Action.

In the present Office Action, the Examiner has again rejected the claimed invention under 35 U.S.C. §102(a) as being anticipated by the Bielinska reference. The Applicants again note that the Examiner has previously acknowledged that the Bielinska reference is a publication of the Applicants' own published within the year before the filing date of the present application, and therefore, is not prior art (see, Restriction Requirement mailed January 13, 2005, page 2). As such, the Applicants respectfully request these rejections be withdrawn, and the claims passed into allowance.

II. Rejection of Claims 25, 26, 28-42, 45-55 and 65 under 35 U.S.C. §103(a)

Claims 25, 26, 28-42, 45-55 and 65 were rejected under 35 U.S.C. §103(a) as being obvious in light of the Foldvari reference, Baker reference, and the Park patent. In particular, the Examiner stated, "Foldvari discloses transdermal delivery of protein or nucleotide to the skin tissue (pp. 71-86).¹ Foldvari discloses on page 205 that dendrimers are known to deliver DNA. Foldvari discloses cutaneous vaccination (title)...The combination of Foldvari and Baker discloses the use of dendrimers for the delivery of proteins or DNA...Skin patch membrane reads on transdermal delivery system and also on Foldvari's cutaneous vaccination (title)." Office Action, pages 3-7. The Applicants respectfully disagree.

None of the references cited by the Examiner, alone or in combination, teach the use of a **skin-patch membrane** associated with at least one dendrimer comprising at least one biological agent comprising nucleic acid, as recited in the claims. As such, none of the references cited by the Examiner teach all of the elements of the claimed invention. The Applicants request these rejections be withdrawn.

The Examiner stated, "Skin patch membrane reads on transdermal delivery system and also on Foldvari's cutaneous vaccination (title)." However, the Foldvari reference does not teach the use of a **skin-patch membrane** associated with at least one dendrimer comprising at least one biological agent comprising nucleic acid, as recited in the claims. On the contrary, the Foldvari reference teaches specific forms of transdermal delivery devices including injection, gene gun delivery, jet injection, microfabricated microneedles, electroporation, sonophoration, and laser pulse delivery as its forms of cutaneous vaccination. See, Foldvari reference at pages

¹ The cited page reference does not pertain to the Foldvari reference.

203-204 ("Delivery Devices"). Of note, the transdermal delivery devices described by the Foldvari reference do not include skin-patch membranes, as required in the claimed invention.

Regarding "reasonable expectation of success," the Examiner stated, "There is thus a reasonable expectation of success that the dendritic delivery systems of both Foldvari and Baker would deliver nucleic acid to the skin tissue cells by the transdermal process, which is topical and to the skin." Office Action, page 7. The Examiner fails to acknowledge or to examine the state of the art at the time of the invention. Indeed, prior to the experiments conducted during the development of embodiments for the present invention (see, e.g., Examples I-XIII), it was unknown whether skin-patch membranes could effectively transfect nucleic acid associated with dendrimers. As the feasibility for such a technology was unknown prior to the filing of the present invention, one skilled in the art would not obtain sufficient guidance from the cited references, alone or in combination, for the purpose of obtaining the claimed invention, nor would there be an expectation of success. For example, the art does not teach or suggest that skin-patch membrane associated dendrimers are bioavailable, stable, or physically oriented so as to have activity. Indeed, the Examiner is failing to address how one skilled in the art could reasonably expect to obtain the claimed invention when none of the cited references teach, suggest, motivate and/or enable the use of skin-patch membranes for such uses.

Regarding "motivation to combine," the Examiner stated, "The motivation to combine the references stems from the ability of the prior art to deliver nucleic acid by transdermal administration." Office Action, page 7. However, the Examiner does not indicate where within the cited references or other evidentiary source such an alleged motivation. In particular, the Examiner fails to indicate why one skilled in the art would be motivated to modify the transdermal delivery devices taught by Foldvari (e.g., injection, gene gun delivery, jet injection, microfabricated microneedles, electroporation, sonophoration, and laser pulse delivery) into a skin-patch delivery system when none of the cited references teach the use of skin-patch delivery systems, when the Foldvari reference provides no alternative delivery systems, and when the Foldvari reference indicates the success of its described transdermal delivery devices.

The Applicants request these rejections be withdrawn.

CONCLUSION

Each rejection of the Office Action mailed June 13, 2007 has been addressed. Should the Examiner believe that a telephone interview would aid in the prosecution of this application Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

Dated: September 13, 2007

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